

REMARKS

Claim Amendments

Claims 1-20 are pending in the present Application. Claim 19 has been amended and Claims 16, 18 and 20 have been canceled in this Response. In particular, Claim 19 has been amended to remove the negative limitation "other than hound dogs, herding dogs, or sporting dogs" and to incorporate the "non-canine" mammal limitation of Claim 20. No new matter has been added.

Upon entry of this amendment, Claims 1-15, 17 and 19 will remain pending in the Application.

Reexamination and reconsideration of the Application as amended are respectfully requested.

Rejection Under 35 U.S.C. § 112

Claims 16 and 18-20 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants have canceled Claims 16, 18 and 20 to obviate the rejection. Further, Claim 19 is amended to remove the negative limitation "other than hound dogs, herding dogs, or sporting dogs" to overcome the rejection. The amended Claim more particularly defines the invention as a method for managing diarrhea in "non-canine" mammals. Reconsideration and withdrawal of the rejection is requested.

Shields, Jr. et al. in view of Wadsworth et al. and Klimberg et al.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as obvious over Shields, Jr. et al. (U.S. Patent No. 6,156,355) in view of Wadsworth et al. (US 2002/082276 A1) and Klimberg et al. (Arch. Surg., 1990). The rejection is traversed for the reasons set forth below.

To establish a *prima facie* case of obviousness based on a combination of references, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of prior art references. Further, when combined, the references must teach or suggest all of the claim limitations. See MPEP 2143.

The present invention is directed to methods and compositions useful in ameliorating diarrhea caused by GI tract inflammation in a mammal. In particular, independent Claim 1 is directed to a composition suitable for oral ingestion by a mammal having GI tract inflammation wherein the composition comprises at least about 0.1% by

weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s). Independent Claim 14 is directed to a method for managing diarrhea in a mammal having GI tract inflammation. The method comprises orally administering to the mammal the composition defined in Claim 1. Independent Claim 19 is directed to a method for managing diarrhea in a non-canine mammal. The method comprises orally administering to the mammal a composition comprising from about 0.1% to about 5% by weight glutamine, from about 0.5% to about 20% by weight fermentable fiber(s), from about 0.1% to about 3% by weight antioxidant(s), and from about 0.1% to about 3% by weight omega-3 fatty acid(s). As further described below, Applicants submit that the present invention defined in independent Claims 1, 14, and 19 is patentable over the cited references because the references do not teach all of the Claim limitations, particularly the required combination and amounts of glutamine, fiber, antioxidants and omega-3 fatty acids, such that a *prima facie* case of obviousness cannot be established. Further, even if a *prima facie* case of obviousness arguably could be established, Applicants can successfully rebut such case by demonstrating unexpected results.

The principal reference, Shields, Jr. et al., discusses breed-specific dog food formulations comprising chicken meat as the major ingredient. Although the reference discusses a single formulation, the "herding diet," which includes fiber, omega-3 fatty acids and antioxidants along with microbial cultures, bromelain (a pineapple extract) and glutamine for breeds that suffer from gastrointestinal immune deficiency, nothing in the reference teaches or suggests ameliorating diarrhea in a mammal having GI tract inflammation. Further, as acknowledged by the Examiner at page 4 of the Office action, the reference is devoid of any teaching regarding specific amounts of glutamine or omega-3 fatty acids. Thus, Applicants submit that the Shields, Jr. et al. fail to provide the necessary teaching or motivation which would lead one skilled in the art to use a composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s).

Applicants respectfully submit that the deficiencies of Shields, Jr. et al. are not overcome by resorting to the teachings of Wadsworth et al. or Klimberg et al. Wadsworth et al. discuss animal food formulations containing *Morinda Citrifolia* extract. Although glutamine is listed as a component of a formulation reported as providing improved

digestive system support, the reference is devoid of any mention of the importance of glutamine in the composition. Further, Wadsworth et al. do not describe glutamine in any formulation comprising fermentable fiber, antioxidants or omega-3 fatty acids as required by the instant Claims. Accordingly, it is respectfully submitted that the cited reference does not provide the necessary teaching or motivation for one skilled in the art to adapt the teachings of Shields, Jr. et al. to arrive at the present invention and any combination of Wadsworth et al. with Shields, Jr. et al. would fail to teach or suggest all of the limitations of the instant Claims. Accordingly, a *prima facie* case of obviousness cannot be established.

Klimberg et al. discuss the administration of glutamine to protect intestinal mucosa of rats from radiation-induced ulceration. Although glutamine is discussed for its healing effects in patients undergoing whole abdominal radiation, nothing in the reference teaches or suggests alleviating diarrhea in a patient suffering from GI tract inflammation. Further, nothing in the reference remotely teaches or suggests any composition comprising glutamine in combination with fermentable fiber, antioxidants or omega-3 fatty acids. Thus, it is respectfully submitted that the cited reference does not provide the necessary teaching or motivation for one skilled in the art to adapt the teachings of Shields, Jr. et al. to arrive at the present invention and any combination of Klimberg et al. with Shields, Jr. et al. would not teach or suggest all of the limitations of the Claims. Accordingly, a *prima facie* case of obviousness cannot be established.

Because the cited references, either alone or in combination, do not adequately teach or suggest any composition for oral administration to a mammal having GI tract inflammation comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s), Applicants submit that the Examiner has failed to establish a *prima facie* case of obvious such that instant Claims 1, 14 and 19 are patentable over Shields, Jr. et al. in view of Wadsworth et al. and Klimberg et al. Reconsideration and withdrawal of the rejection are requested.

Applicants still further submit that, even if a *prima facie* case of obviousness can be shown, Applicants can sufficiently rebut any such showing by demonstrating unexpected results. In particular, in Example 2 on pages 4 and 5 of the specification, Applicants have shown that the specific combinations and amounts of glutamine, fermentable fiber(s), omega-3 fatty acid(s) and antioxidant(s) of the present invention are particularly effective in ameliorating diarrhea caused by GI tract inflammation in a mammal. In particular, the

example describes "Food C" which comprised all four components of the composition of the present invention as demonstrating "significantly better results in stool quality" over three control formulations (Foods A, B and D) which were missing at least one of the four components. Such unexpected results are sufficient to rebut any arguable showing of a *prima facie* case of obviousness provided by the cited references. Accordingly, Applicants request reconsideration and withdrawal of the rejection of Claims 1, 14 and 19 under 35 U.S.C. §103(a).

Claims 2-13, 15 and 17, which depend in whole or in part from Claims 1, 14, and 19, are submitted to be patentable over the cited references for at least the same reasons as set forth above with respect to Claims 1, 14 and 19.

Chandler

Claims 1-20 are rejected under 35 U.S.C. 103(a) as obvious over Chandler (In Practice, 2002). Reconsideration and withdrawal of the rejection is requested.

Applicants submit that the present invention is patentable over Chandler because the reference does not teach all of the claim limitations, particularly the required combination and amounts of glutamine, fiber, antioxidants and omega-3 fatty acids, such that a *prima facie* case of obviousness cannot be established. Chandler generally discusses various dietary modifications which may be useful in treating gastrointestinal disorders in dogs and cats. However, Chandler does not provide any particular teaching with respect to amounts or combinations of dietary modifications which may be suitable for any particular conditions. Chandler certainly does not provide any teaching or motivation to prepare a composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) as required by the instant Claims. Thus, one skilled in the art reading Chandler would not arrive at the present invention without reference to Applicants' disclosure such that a *prima facie* case of obviousness cannot be established. Accordingly, Applicants submit that the invention of Claims 1-20 is patentable over the cited reference.

Further, Applicants submit that, even if a *prima facie* case of obviousness can be shown, Applicants can sufficiently rebut any such showing by demonstrating unexpected results. As described above, Applicants have demonstrated in Example 2 on pages 4 and 5 of the specification that the specific combinations and amounts of glutamine, fermentable fiber(s), omega-3 fatty acid(s) and antioxidant(s) of the present invention are particularly

effective in ameliorating diarrhea caused by GI tract inflammation in a mammal. Such unexpected results are sufficient to rebut any arguable showing of a *prima facie* case of obviousness provided by Chandler. Accordingly, Applicants submit that Claims 1-20 are patentable over the cited reference. Reconsideration and withdrawal of the rejection of Claims 1-20 under 35 U.S.C. §103(a) is requested.

Conclusion

In summary, the rejections under 35 U.S.C. §112 and §103 has been obviated or overcome. In view of the foregoing Remarks, it is submitted that the Claims are in condition for allowance. Reexamination and reconsideration of the Application as amended are requested and allowance of the Claims at an early date is solicited.

If the Examiner believes that personal communication will expedite prosecution of this Application, the Examiner is invited to call the undersigned at the number listed below.

Respectfully submitted,



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